

## Commentary: Unnecessary preoperative epidural steroid injections lead to cerebrospinal fluid leaks confirmed during spinal stenosis surgery

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Received: 09 June 14 Accepted: 11 June 14 Published: 28 August 14

### This article may be cited as:

Epstein NE. Commentary: Unnecessary preoperative epidural steroid injections lead to cerebrospinal fluid leaks confirmed during spinal stenosis surgery. *Surg Neurol Int* 2014;5:S325-8.

Available FREE in open access from: <http://www.surgicalneurologyint.com/text.asp?2014/5/8/325/139622>

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### ABSTRACT

**Background:** Increasingly, older patients with severe spinal stenosis/instability undergo multiple unnecessary preoperative epidural spinal injections (ESI), despite their risks and lack of long-term benefits. Here we add to the list of risks by showing how often preoperative ESI lead to punctate cerebrospinal fluid (CSF) fistulas documented during subsequent surgery (e.g. multilevel laminectomies with non-instrumented fusions).

**Methods:** A series of 39 patients with spinal stenosis/instability prospectively underwent multilevel laminectomy/non-instrumented fusion utilizing lamina autograft and NanOss Bioactive. We asked how often preoperative ESI were performed in this population and how frequently they contributed to operatively confirmed punctate cerebrospinal fluid (CSF) fistulas. Notably, CSF leaks were clearly attributed to ESI, as they were located centrally/paracentrally at the L4-L5 level, just below hypertrophied/ossified yellow ligament (OYL), and were the exact size of a Tuohy needle with clean edges.

**Results:** An average of 4.1 (range 2-12) preoperative ESI were performed in 33 of 39 patients undergoing average 4.3 level laminectomies and 1.3 level non-instrumented fusions; 6 (18.2%) patients exhibited operatively confirmed, punctate CSF fistulas attributed to these ESI. The most recent injections were administered between 2 and 5 weeks prior to surgery (average 3.9 weeks). Fistulas were primarily repaired with 7-0 GORE-TEX sutures and fibrin Sealant (Tisseel).

**Conclusions:** Of 33 patients undergoing multilevel laminectomies with non-instrumented fusions receiving preoperative ESI, 6 (18.2%) had operatively confirmed punctate CSF fistulas due to preoperative ESI performed an average of 4.1 times per patient.

**Key Words:** Epidural steroid injections, fistulas, operative confirmation, punctate cerebrospinal fluid leaks, spinal surgery

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online

Website:

[www.surgicalneurologyint.com](http://www.surgicalneurologyint.com)

DOI:

10.4103/2152-7806.139622

Quick Response Code:



## INTRODUCTION

Patients are increasingly seeking not only single, but multiple epidural spinal injections (ESI) prior to considering almost any type of lumbar surgery. This is particularly true for older patients with multilevel lumbar stenosis/instability who are hoping to avoid surgery. However, much of the literature documents that these injections are unnecessary and ineffective in providing long-term benefits, while also subjecting older patients with major comorbidities to increased risks. Here, we studied how often patients undergoing multilevel laminectomies with non-instrumented fusions exhibited operatively confirmed, punctate cerebrospinal fluid (CSF) fistulas directly attributed to their multiple preoperative ESI injections.

## MATERIALS AND METHODS

In our series, 39 patients with symptoms/signs of lumbar stenosis/instability underwent multilevel laminectomies with non-instrumented fusion utilizing lamina autograft and NanOss Bioactive (Pioneer Surgical, Marquette MI, USA) [Table 1]. We focused on the 33 patients who had undergone preoperative ESI, and asked how often they later exhibited operatively confirmed, punctate CSF fistulas that could be directly attributed to preoperative ESI. These ESI-induced punctate fistulas, were the same size as the tip of an 18-gauge Tuohy needle, had “clean” edges, and were typically located centrally/paracentrally at the L4-L5 level often initially hidden under hypertrophied/ossified yellow ligament (OYL).

### Clinical parameters

Patients (comprising 10 males and 23 females) averaged 65.8 years of age and were followed an average of 1.42 months (range 7-22 months) [Table 1]. Surgical procedures included an average of 4.3 level laminectomies and 1.3 level (range 1-2 level) non-instrumented fusions. Spinal stenosis was accompanied by ossification of the yellow ligament (all 33 patients), disc herniations (12 patients), and unilateral synovial cysts (3 patients). Instability was variously attributed to: far lateral discs warranting a unilateral full facetectomy (1 patient), spondylolisthesis/lysis (3 patients), or spondylolisthesis alone (29 patients).

## RESULTS

### Preoperative ESI resulted in intraoperative punctate CSF fistulas in six patients

Thirty-three patients received an average of 4.1 ESI prior to spine surgery (range 2-12 ESI/patient) [Table 1]. Six patients had punctate CSF leaks confirmed intraoperatively that were directly

**Table 1: Clinical data for multilevel laminectomies/non-instrumented fusions with/without Tisseel**

Variable	Patients receiving Tisseel (33 patients)
Average age (range)	65.8 (46-82)
Sex	
Males	10
Females	23
Average follow-up	
Range	14.2 months
Cerebrospinal fluid leaks due to Epidural steroid injections (ESI)	7-22 months
Number receiving ESI	6
Average number ESI	33
Range of ESI	4.1
Average weeks preoperatively	2-12
Range of most recent injections	3.9 weeks
Levels of stenosis/laminectomy for stenosis	
Specific levels	4.3
L1-S1	8
L2-S1	7
L3-S1	12
L4-S1	3
L1-L3	1
L3-L5	2
Disc herniations	12
Unilateral L45 synovial cysts	3
Far lateral disc/facetectomy	1
Olisthy/spondylolysis L5S1	3
Degenerative spondylolisthesis	29
Average levels of in situ fusions	1.33
Single level fusions	23
Two level fusions	10

ESI: Epidural steroid injections

attributed to prior ESI; the most recent injections were performed an average of 3.9 weeks prior to surgery (range 2-5 weeks). Dural lacerations were directly repaired under an operating microscope with 7-0 GORE-TEX sutures (W. L. Gore and Associates, Newark, DE, USA) to achieve watertight closures. The fibrin sealant Tisseel (Baxter International Inc., Westlake Village, CA, USA) supplemented the dural closure utilizing the “sandwich technique.” This technique required that 5 of the 10 cc of Tisseel be evenly applied in a thin layer directly over the dura, followed by one layer of microfibrillar collagen (Duragen: Integra LifeSciences Corporation, Plainsboro Township, NJ, USA), and finally succeeded by the last and final layer of the remaining 5 cc of Tisseel.<sup>[19]</sup>

## DISCUSSION

In this study, we observed that 33 patients undergoing multilevel laminectomies received an average of 4.1

ESI; 6(18.2%) patients exhibited intraoperative punctate dural fistulas directly attributed to these injections. The extraordinarily high number of ESI in these patients and the high resultant frequency of punctate CSF fistulas indicate just how often patients are being “overtreated” by too many “providers with unnecessary, ineffective, and invasive ESI that put them at increased risk. Fortunately in this series, the six punctate ESI leaks only increased the operative time by 20 min, but did not result in other major sequelae. Nevertheless, the four patients with cardiac disease/coated stents who underwent typically multiple preoperative ESI had to stop anti-platelet therapy prior to each ESI thereby putting them at increased risk of thrombosis/myocardial infarction. Furthermore, delaying surgery, often for years (e.g. one patient delayed surgery by 6 years undergoing 12 ESI), can contribute to more severe, irreversible neurological deficits that cannot be recouped.

### High frequency of unnecessary lumbar ESI

Rosas *et al.* noted that lumbar radicular/sciatic complaints impact 13% of Americans per year, and noted that back pain is the second most common symptom-related cause for medical office visits in the United States.<sup>[14]</sup> Epstein noted that although not approved by the Food and Drug Administration (FDA), injections are being performed with an increased frequency (up 160%) and are typically short acting, are ineffective over the longer term, and expose patients to major risks/complications.<sup>[7]</sup>

### 18.2% Risk of intraoperative punctate dural tears secondary to preoperative ESI in patients with lumbar stenosis/instability

The incidence of durotomies occurring during spinal surgery varies from 1 to 9% for open procedures, increasing to 9.4% for minimally invasive surgery (MISS) and up to 21% for open reoperations.<sup>[5,8,10,15]</sup> To this list we now add an 18.2% risk of encountering intraoperative punctate CSF fistulas due to preoperative ESI for patients with spinal stenosis/instability undergoing multilevel laminectomies/non-instrumented fusions. For these patients, Tisseel can be applied to supplement the repair of these CSF fistulas utilizing the “sandwich technique.”<sup>[3,13,16,17,19]</sup>

### ESI have no long-term benefits, but correlate with major complications

Multiple studies have already demonstrated no long-term benefits of ESI, while they pose increased risks/complications. Landa *et al.* found that cervical and lumbar ESI demonstrated efficacy for up to 6 months of pain relief, though long-term benefits are less reliable, and acknowledged that these injections can also result in severe complications.<sup>[11]</sup> In a randomized, double-blind trial, Carrette *et al.* showed that utilizing three ESI (methylprednisolone acetate 80 mg/8 ml of isotonic saline) versus isotonic saline (1 ml) alone were

equally ineffective in managing sciatica in 158 patients at 3, 6, 12 weeks, and 1 year; there were no significant differences in outcomes for the two groups.<sup>[6]</sup> In Arden *et al.*'s multicenter, double-blind, randomized study of 228 patients over 1 year, the efficacy of three lumbar ESI versus three interligamentous saline injections were compared.<sup>[2]</sup> Utilizing the Oswestry Disability questionnaire (ODI), at 3 weeks, the steroid group showed a transient benefit over the placebo group; however, from 6 to 52 weeks post-injection, no benefits were demonstrated. Similarly, in Anderberg *et al.*'s prospective randomized study of 40 patients undergoing cervical ESI/local anesthetic versus sterile saline/local anesthetic, at five post-injection weeks, patients receiving steroid injections had less pain, but this did not last over the long term.<sup>[1]</sup>

### Complications of ESI include CSF leaks/dural fistulas

Cervical or lumbar ESI may directly contribute to inadvertent CSF fistulas. In Botwin *et al.*'s study, complications of cervical interlaminar epidural spinal injections included<sup>[16]</sup> non-positional headaches (likely due to CSF leaks) (4.6%) and one dural puncture (0.3%).<sup>[4]</sup> In Waldman's series of 790 cervical epidural injections performed in 215 patients, there were two dural punctures.<sup>[18]</sup>

### Frequency of dural puncture for ESI administered in labor/delivery

In a survey of 36 academic institutions involving 137,250 women undergoing epidural analgesia for labor/deliveries, Berger *et al.* found the frequency of inadvertent dural punctures ranged from 0.4-6%.<sup>[3]</sup> Webb *et al.* also reported a comparable maximum risk of inadvertent dural puncture utilizing a 17-gauge Tuohy needle for epidurals performed for labor/delivery.<sup>[20]</sup>

### Multiple complications of ESI are often underreported

In animal models and clinical studies, ESI penetrating the dura result in a multitude of complications. In a dog model, Lima *et al.* performed intrathecal injections of normal saline versus methylprednisolone; the latter resulted in meningeal thickening, lymphocytic infiltrates in the blood vessels, and adhesions of pia, arachnoid, and dura mater with nerve roots surrounded by fibrosis and necrosis of the spinal cord.<sup>[12]</sup> In multiple clinical studies, ESI resulted in many more serious complications that were often underreported: infection (epidural abscess, meningitis), epidural hematoma, intravascular injections, nerve damage, CSF fistulas/headaches, air embolism, urinary retention, allergic reactions, seizures, blindness, and others.<sup>[3,9,11,20,21]</sup>

## CONCLUSION

The purpose of this commentary was to highlight two major issues. First, there are too many ESI being performed

prior to lumbar surgery for stenosis/instability; in this study of the 33 patients undergoing lumbar laminectomy with non-instrumented fusions, an average of 4.1 ESI were performed per patient. An average of 4.1 ESI per patient. It has been well established that ESI are unnecessary/ineffective over the long term and unnecessarily expose these patients to increased risks/complications. Second, performing multiple preoperative ESI, as demonstrated in this series, resulted in too many intraoperative, punctate CSF fistulas [6 (18.2%)] that could have potentially increased perioperative morbidity. When does “restraint” regarding the performance of such multiple ESI begin?

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